

REMARKS/ARGUMENTS

Claims 1-5, 7-9, and 11-12 are pending

Rejection under 35 USC §102

Claims 1-3, 5, 7-9 and 11-12 stand rejected as allegedly anticipated by Dabal et al. Applicants respectfully disagree.

Anticipation can only be established by a single prior art reference which discloses each and every element of the claimed invention (*See, RCA Corp. v. Applied Digital Data Systems, Inc.*, 730 F.2d 1440, 1444 (Fed. Cir. 1984)). "The identical invention must be shown in as complete detail as is contained in the patent claim" (*Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989)). It is not enough, however, that the reference discloses all the claimed elements in isolation. Rather, as stated by the Federal Circuit, the cited art reference must disclose each element of the claimed invention "arranged as in the claim" (*Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983)).

Claim 1 recites:

A process for producing tablets by melt extrusion, in which an extrudable pharmaceutical mixture is heated and extruded in the form of a continuous product strip, wherein, in a first stage, the still deformable product strip is compressed to a continuous tablet belt, the individual tablets in the belt being connected together by product webs, in a second stage, downstream of the first stage, the tablet belt is allowed to cool to form a solidified tablet belt, in a third stage, downstream of the second stage, the tablets are mechanically singulated in a continuous process, and then the singulated tablets are transported further to a fourth stage downstream of said third stage where the singulated tablets are subsequently deflashed.

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art (*See, In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)).

Applicants respectfully assert that the cited art reference fails to disclose each and every element of the claimed invention. The cited art fails to disclose at least the following:

1) an extrudable pharmaceutical mixture is heated and extruded in the form of a continuous product strip;

2) a continuous product strip, wherein, in a first stage, the still deformable product strip is compressed to a continuous tablet belt; and

3) in a second stage, downstream of the first stage, the tablet belt is allowed to cool to form a solidified tablet belt.

In regards to the failure to disclose an extrudable pharmaceutical mixture is heated and extruded in the form of a continuous product strip, the Examiner is directed to FIG. 1, column 10, lines 47 et. seq. and column 15, lines 45 et seq. Turning first to FIG. 1, Applicants respectfully assert that the figure shows a pathway for production of an active ingredient in step 12 and in a separate pathway, a step for web production, step 10. Only after an active ingredient and a web are produced does deposition of active ingredients occur in the web as shown in step 14. Next, column 10 describes a means of storage of active ingredient until such time as the active ingredient is deposited on the web. More specifically, in regards deposition of active ingredient in the web, column 10 states that it is a "uniform deposition (block 14 of FIG. 1) of the active ingredient on the web" and thus provides further evidence of the separate steps of active ingredient production and web production. Third, Dabal et al., in describing the lack of a need for pharmaceutical excipients, states in column 15 that "the active ingredient is deposited on or substantially on the surface of an edible web." Additionally, claim 1 of Dabal et al. recites in (a), a "first means for producing a web of edible, therapeutically inert material" and in (b), a "second means receiving said web for loading to said web at least one medicament" further demonstrating the separate pathways and steps required for the cited art to fabricate dosage forms. Accordingly, Dabal et al. fails to anticipate the instant claimed invention because it fails to teach, suggest or disclose an extrudable pharmaceutical mixture is heated and extruded in the form of a continuous product strip.

Further, dissimilar to the instant claimed invention, the fabrication step disclosed in Dabal et al. has to resolve the problem of not only producing tablets, but also to "internalize" the pharmaceutical coating within the preformed web (*See*, col. 19, ll. 19-20). Applicants respectfully assert that Dabal et al. fails to disclose a continuous product strip, wherein, in a first stage, the still deformable product strip is compressed to a continuous tablet belt, rather the disclosed production requires in each case (e.g., the variant of FIG. 4 or the variant of FIG. 5) that stacks of webs coated with active ingredient be employed in order to allow for a suitable

internalization of the coating containing the active ingredients.

Moreover, Dabal et al. fails to teach, suggest or disclose in a second stage, downstream of the first stage, the tablet belt is allowed to cool to form a solidified tablet belt. Applicants respectfully assert that FIG. 5 fails to teach, suggest or disclose any type of ambient cooling. The Examiner asserts that "ambient cooling will take place along the transport sections," but a review of FIG. 4 shows that no "transport section" is foreseen between the fabrication step and the unitizing step. Moreover, in column 22, lines 18-19, the cited art recites that the rods (endless strip, stack) "are passed through printing and unitizing stations or subassemblies, all at high speed" failing to allow for ambient cooling. If the Examiner has personal knowledge regarding ambient cooling, Applicants respectfully request submission of an Examiner's affidavit and thereafter be provided a full and fair opportunity to respond. In the absence of such evidence or an affidavit, Applicants respectfully request that this rejection be withdrawn. Accordingly, Dabal et al. fails to teach, suggest or disclose a second stage, downstream of the first stage, the tablet belt is allowed to cool to form a solidified tablet belt and thus, fails to anticipate the instant claimed invention.

Similar to the assertions above, Applicants respectfully submit Dabal et al. fails to anticipate the apparatus of claim 12. More specifically, the cited art reference fails to teach, suggest or disclose the limitations of claim 12 "arranged as in the claim." Accordingly, Applicants respectfully request withdrawal of the instant anticipation rejection and favorable action is solicited.

Further still, Dabal et al. fails to teach suggest or disclose a force with a component perpendicular to the plane of the tablet belt is allowed to act on the tablet belt for singulation of the tablet of claims 2-5. The cited art references discloses "ultrasharp knives" (col. 21, l. 45), "rollers" (col. 22, l. 3) and a "rotary forming technique" (col. 22, l. 21 and col. 23, ll. 66-68). In regards to claim 7, Dabal et al. fails to teach, suggest or disclose at least one rotatable roller for diverting the tablet belt out of a transport plane of the first transport means. Additionally, Dabal et al. fails to teach, suggest or disclose a second transport means is provided between the singulating means and the deflashing means and comprises a shaking or vibrating unit of claim 11.

In view of at least the above, because Dabal et al. fails to teach, suggest or disclose each

and every element of at least claims 1 and 12, it does not anticipate claims 1 and 12 and the claims dependent therefrom. Applicants therefore respectfully request withdrawal of the rejection under 35 USC § 102(b). Favorable action is solicited.

Rejection under 35 USC §103

Claim 4 stands rejected as unpatentable over Dabal et al. in view of Klimesch et al. Applicants respectfully disagree.

To establish *prima facie* obviousness, the Examiner must show in the prior art some suggestion or motivation to make the claimed invention, a reasonable expectation for success in doing so, and a teaching or suggestion of each Claim element (*See, e.g., In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ 2d 1941 (Fed. Cir. 1992); *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986); *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)). Most inventions arise from a combination of old elements and each element may often be found in the prior art (*In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998)). However, mere identification in the prior art of each element is insufficient to defeat the patentability of the combined subject matter as a whole (*Id.* at 1355, 1357). Rather, to establish a *prima facie* case of obviousness based on a combination of elements disclosed in the prior art, the Examiner must articulate the basis on which it concludes that it would have been obvious to make the claimed invention (*Id.*). In practice, this requires that the Examiner "explain the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them to render the claimed invention obvious" (*Id.* at 1357-59). This entails consideration of both the "scope and content of the prior art" and "level of ordinary skill in the pertinent art" aspects of the *Graham* test.

Independent claim 1 stands free of *prima facie* obviousness. Claim 4 depends from claim 1 and as such, also stands free of *prima facie* obviousness. As the Federal Circuit stated in *In re Fine*, "[d]ependent claims are nonobvious under section 103 if the independent claims from which they depend are nonobvious" (837 F.2d at 1076). Accordingly, because *prima facie* obviousness has not been established, Applicants respectfully request withdrawal of the 103 rejection.

Application No.: 09/787,079
Inventor: ROSENBERG et al.
Reply to Office Action of 17 January 2006
Docket No.: 0480/01216

Conclusion

Applicants respectfully submit that the present application is in condition for allowance, which action is courteously requested. Please charge the three-month extension fee to the credit card listed on the enclosed Form PTO-2038. Please charge any shortage in fees due in connection with the filing of this paper to Deposit Account 14.1437. Please credit any excess fees to such account.

Respectfully submitted,



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